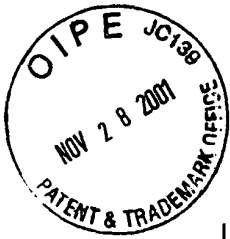


Attorney Docket No.: US 1257/01 (VA)



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of : November 28, 2001
Theresa H. SMITH, Ph.D. :
Serial No.: 09/931,009 :
Filed: August 17, 2001 :
For: PRO-INFLAMMATORY :
FIBRINOPEPTIDE :

SUPPLEMENTAL
INFORMATION DISCLOSURE STATEMENT

Honorable Commissioner of Patents
Washington, D.C. 20231

Dear Sir:

Pursuant to 37 CFR 1.56 and 1.97-1.98, Applicant submits herewith copies of various references for the Examiner's consideration. These references are cited in the application as "REFERENCES". The Examiner is respectfully requested to review and officially consider and make the references of record before issuing the first Office Action in connection with this case.

A completed PTO form 1449B/PTO listing the references thereon together with copies of same is enclosed herewith. The Examiner is respectfully requested to return

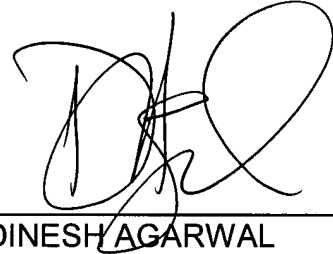
S.N. 09/931,009

an initialed copy of PTO form 1449B/PTO along with the next communication in connection with this case.

It is believed that no fee is due for this submission. Should that determination be incorrect, however, the Examiner is hereby authorized to charge any deficiencies to our Deposit Account No. 01-0433, and notify the undersigned in due course.

Should the Examiner have any questions or wish to discuss further this matter, please contact the undersigned at the telephone number provided below.

Respectfully submitted,

A handwritten signature in black ink, appearing to be 'D. Agarwal', written over a horizontal line.

DINESH AGARWAL
Attorney for Applicant(s)
Reg. No. 31,809

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DA/mm

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C mplete if Known

Application Number	09/931,009
Filing Date	August 17, 2001
First Named Inventor	Theresa M. SMITH, Ph.D.
Group Art Unit	1646
Examiner Name	
Attorney Docket Number	US 1257/01 (VA)

Sheet **1** of **4**

[illegible][illegible]Date
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¹ Unique citation designation number. ² See attached Kinds of U.S. Patent Documents. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3) ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.1 ⁶ if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

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Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

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1449B/PTO Rev. 10/95		U.S. Department of Commerce Patent and Trademark Office		Complete if Known	
LIST OF PRIOR ART CITED BY APPLICANT (use as many sheets as necessary)				Application Number	09/931,009
				Filing Date	August 17, 2001
				First Named Inventor	Theresa M. SMITH, Ph.D.
				Group Art Unit	1646
				Examiner Name	
Sheet	2	of	4	Attorney Docket Number	US 1257/01 (VA)

OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS			
Examiner Initials ¹	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book), magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), Publisher, country, where published, source.	T ²
		Colvin RB, Johnson RA, Mihm MC, and Dvorak HF. <u>Role of the Clotting System in Cell-Mediated Hypersensitivity</u> . J Exp Med 1973, 138:686-698.	
		Accini L, Dixon FJ. <u>Degenerative Vascular Disease and Myocardial Infarction in Mice with Lupus-like Syndrome</u> . Am J. Pathol 1979, 96:477-492.	
		Wood RM, Bick MW. <u>The Effect of Heparin on the Ocular Tuberculin Reaction</u> . Arch Opthamol 1959, 61:709-711.	
		Cohen SB, Benacerraf B, McCluskey RT, Ovary Z. <u>Effects of Anticoagulants on Delayed Hypersensitivity Reaction</u> . J Immunol 1967, 98:351-358.	
		Colvin RB, Dvorak HF. <u>Role of the Clotting System in Cell-Mediated Hypersensitivity II. Kinetics of Fibrinogen/fibrin Accumulation and Vascular Permeability Changes in Tuberculin and Cutaneous Basophil Hypersensitivity Reactions</u> . J Immunol 1975, 114:377-387.	
		Edwards RL, and Rickles FR. <u>Delayed Hypersensitivity in Man: Effects of Systemic Anticoagulation</u> . Science 1978, 200:541-543.	
		Colvin RB, Mosesson MW, Dvorak HF. <u>Delayed Type Hypersensitivity Skin Reactions in Congenital Afibrinogenemia Lack Fibrin Deposition and Induration</u> . J Clin Invest 1979, 63:1302-1306.	
		Malik AB, Johnson A, Tahamont MV. <u>Mechanisms of Lung Vascular Injury After Intravascular Coagulation</u> . Ann NY Acad Sci 1982, 384:213-234.	
		Kay AB, Pepper DS, McKenzie R. <u>The Identification of Fibrinopeptide B as a Chemotactic Agent Derived from Human Fibrinogen</u> . Br J Hematol 1974, 27:669-677.	
		Richardson DL, Pepper DS, Kay AB. <u>Chemotaxis for Human Monocytes by Fibrinogen Derived Peptides</u> . Br J Hematol 1976, 32:507-513.	
		Sueishi K, Nanno S, Tanaka K. <u>Permeability Enhancing and Chemotactic Activities of Lower Molecular Weight Degradation Products of Human Fibrinogen</u> . Thromb Haemost 1981, 45:90-94.	

Examiner Signature		Date Considered	
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Examiner Initials ¹	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book), magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), Publisher, country, where published, source.	T ²
		Rowland F, Donovan M, Gillies C, O'Rourke J, Kreutzer DL. <u>Fibrin: Mediator of In Vivo and In Vitro Injury and Inflammation.</u> Curr Eye Res 1985, 4:537-553.	✓
		Saxne T, Lecander I, Geborek P. <u>Plasminogen Activators and Plasminogen Activator Inhibitors in Synovial Fluid Difference Between Inflammatory Joint Disorders and Osteoarthritis.</u> J Rheumatol 1993, 20:91-96.	✓
		Kikuchi H, Tanaka S, Matsuo O. <u>Plasminogen Activator in Synovial Fluid from Patients with Rheumatoid Arthritis.</u> J Rheumatol 1987, 14:439-445.	✓
		Kummer JA, Abbink JJ, De Boer JP, Roem D, Nieuwenhuys EJ, Kamp AM, Swaak TJG, Hack CE. <u>Analysis of Intraarticular Fibrinolytic Pathways in Patients with Inflammatory and Noninflammatory Joint Diseases.</u> Arthritis Rheum 1992, 35:884-893.	
		Belch JJF, McArdle B, Madhok R. <u>Decreased Plasma Fibrinolysis in Patients with Rheumatoid Arthritis.</u> Ann Rheum Dis 1984, 43:774-777.	
		Dahlquist SR, Jonsson SW, Ranby M. <u>Fibrinolytic Components in Synovial Fluid of Destructive and Non-Destructive Arthritis.</u> Arthritis Rheum 1994, 37:S248.	✓
		Herrick AL, Illingworth K, Blann A, Hollis S, Jayson MIV. <u>Von Willebrand Factor, Thromboxane, B-Thromboglobulin and Markers of Fibrinolysis in Primary Raynaud's Phenomenon and Systemic Sclerosis.</u> Arthritis Rheum 1994, 37:S259.	✓
		Qi J, Kreutzer DL, Piela-Smith TH. <u>Fibrin Induction of ICAM-1 Expression in Human Vascular Endothelial Cells.</u> J Immunol 1997, 158:1880-1886.	✓
		Kawasaki K, Hirase K, Masanori M, Tsuji T, Iwamoto, M. <u>Amino Acids and Peptides XVI. Synthesis of N-terminal Tetrapeptide Analogs of Fibrin a Chain and Their Inhibitory Effects on Fibrinogen/fibrin Clotting.</u> 1992. Chem Pharm Bull 40:3253-3260.	✓
		Cliffon EE, Grossi CE. <u>The Rationale of Anticoagulants in the Treatment of Cancer.</u> J Med 1974, 5:107-113.	✓
		Peterson HI. <u>Fibrinolysis and Antifibrinolytic Drugs in the Growth and Spread of Tumors.</u> Cancer Treat Rev 1977, 4:213-217.	✓

Examiner Signature	Date Considered
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		Zacharski LR, Henderson WG, Rickles FR, Forman WB, Cornell CJ Jr, Forcier RJ, Edwards R, Headley E, Kim SH, O'Donnell JR, O'Dell R, Tornyo K, Kwaan HC. <u>Effect of Warfarin on Survival in Small Cell Carcinoma of the Lung.</u> JAMA 1981, 245:831-835.	✓
		Bardos H, Juhasz A, Repassy G, Adany R. <u>Fibrin Deposition in Squamous Cell Carcinomas of the Larynx and Hypopharynx.</u> Thromb Haemost 1998, 80:767-772.	✓
		Laudano AP, Doolittle RF. <u>Studies on Synthetic Peptides That Bind to Fibrinogen and Prevent Fibrin Polymerization. Structural Requirements, Number of Binding Sites, and Species Differences.</u> 1980, Biochemistry 19:1013-1019.	✓
		Shreck R, Meier B, Manne D, Droge W, Bauerle PA. <u>Dithiocarbamate as Potent Inhibitors of Nuclear Factor kB in Intact Cells.</u> J Exp Med 1992, 175:1181-1194.	✓
		Lorenz H-M, Kalden JR. <u>Biologic Agents in the Treatment of Inflammatory Rheumatic Diseases.</u> 1999, Curr Opin Rheumatol 11:179-184.	
		Rothchild, BM, Thompson, LD, Pifer DD, Chesney CM. <u>Perturbation of Protease Inhibitors and Substrates in Inflammatory Arthritis.</u> Semin Thromb Hemostasis 1985, 11:394-404.	
		Belch JJF, Madhok R, McArdle B, McLaughlin K, Kluft C, Forbes CD, Sturrock RD. <u>The Effect of Increasing Fibrinolysis in Patients with Rheumatoid Arthritis: A Double Blind Study of Stanozolol.</u> Q J Med 1986, 58:19-27.	

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